

Legal proceedings started against patents on human embryonic stem cells and interventions in the human germ line

Case brought before the German Federal patent court and opposition filed at European Patent Office

20 February 2020 / Testbiotech has started legal proceedings in two cases against patents. The cases were initiated to clarify fundamental ethical questions in patent law, especially in regard to the protection of human dignity. A case was filed at the German Federal patent court (Bundespatentgericht) in a bid to nullify the German patent (DE102004062184), which claims uses of human embryos to obtain stem cells. In addition, Testbiotech has filed an opposition to a European patent on uses of the so-called CRISPR/Cas gene scissors; the well-known scientists Jennifer Doudna and Emmanuelle Charpentier are named as the inventors in this patent (EP3401400). The human germ line and the commercial use of human embryos are not definitively excluded in this patent as required in law. In addition, the patent claims the application of CRISPR/Cas on plants and animals.

Patents on commercial uses of human embryos and interventions in the human germ line are strictly prohibited in Europe. However, the submitted legal analysis has revealed that the prohibitions were not sufficiently taken into consideration in the granting of these patents. Testbiotech warns that the patents not only contravene patent law but may also lead to unethical commercial incentives. Against the backdrop of the broad range of potential applications for the new methods of genetic engineering, the protection of ethical boundaries is of utmost importance.

“The protection of human dignity has become a crucial issue now that the new methods of genetic engineering, such as CRISPR/Cas gene scissors, have become available. Ethical standards are under attack wherever experiments with human life are conducted, not only in China. Under these circumstances, the patent offices should strictly avoid sending the wrong signals that might lead to questionable incentives,” says Christoph Then for Testbiotech.

The legal analysis of the patent attorneys representing Testbiotech shows that European patent EP3401400 is based on broad claims, and also covers interventions in the human germ line and use of human embryos to obtain embryonic stem cells. There is a short paragraph in the patent description which states that human germ cells and human embryonic stem cells are not comprised. However, this statement is not backed up by the overall technical description and the claims in the patent. Therefore, Testbiotech is demanding the revocation of the patent or at least substantial changes in the claims to establish legal certainty.

Patent DE102004062184 was granted by the German Patent Office, while the parallel application was rejected by the European Patent Office (EPO). The patent was granted to a reproductive endocrinologist in Munich. The patent claims the usage of human embryos to obtain human embryonic stem cells which are highly sought after for various research purposes. Covered by the patent is also the usage of human embryos derived from the process of *in vitro* fertilisation. The process described in the patent would be liable for prosecution under German law for the protection

of human embryos, reflecting the importance of ethical boundaries for the legislator. Therefore, Testbiotech is demanding that the patent is nullified in respect to human embryos.

Ruth Tippe represents the initiative ‘No Patents on Life!’ that has for many years conducted patent research at the EPO. She is also affiliated with Testbiotech. She warns that the patents mentioned above are not just individual cases. According to her research, in 2019, the EPO granted several further patents on the application of the new methods of genetic engineering with similar claims to the European patent as now being under opposition. According to her research, the number of patent applications for embryonic stem cells and genetically engineered plants per year is increasing. Patent applications for genetically engineered animals were decreasing a few ago, but are now stable at a relatively high level.

In recent years, Testbiotech has been successful with several oppositions against patents at the EPO. Cases still pending include patents on genetically engineered animals, a number of them on chimpanzees. Some of these cases are scheduled for decision in a public hearing on 10 July this year. Testbiotech that believes there is an urgent need for changes in the way the European Patent Office grants patents on plants and animals. The European patent EP3401400 also claims the application of the gene scissors to plants and animals.

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Further information

Patent EP3401400:

<https://data.epo.org/publication-server/pdf-document?pn=3401400&ki=B1&cc=EP&pd=20190403>

Text of opposition (in German):

https://www.testbiotech.org/sites/default/files/19019OWWGS_Einspruchsschriftsatz.pdf

Patent DE102004062184 (in German):

https://www.testbiotech.org/sites/default/files/DE102004062184B4_0.pdf

Text of legal challenge (in German):

https://www.testbiotech.org/sites/default/files/18029NiWWGS_Patentnichtigkeitsklage.pdf

Overview on patent applications on human embryonic stem cells, plants and animals

<https://www.testbiotech.org/content/uebersicht-ueber-patentanmeldungen-epa>

Further pending patent cases of Testbiotech:

<https://www.testbiotech.org/en/content/legal-cases-0>